REMARKS

This Amendment cancels claims 1 and 3-7, rewrites claims 16 and 20, and adds new claim 34. Page 5, lines 18-20 support the amendment of claims 16 and 20. The correlation step of new claim 34 is disclosed by Figs. 8, 10 and 12-14, taken in view of the specification as a whole. Claims 16 and 18-34 are pending.

Examiner Fubara is thanked for the courtesies extended to the undersigned during a personal interview held October 21, 2004. The Examiner Interview Summary Record accurately reflects the substance of the interview.

The 35 U.S.C. § 102(b) rejection of claims 1 and 3-7 over U.S. Patent No. 4,919,871 to Lin et al. is mooted by the cancellation of those claims. Reconsideration and withdrawal of the anticipation rejection of claims 1 and 3-7 over Lin et al. are earnestly requested.

The 35 U.S.C. § 102(b) rejection of claims 1, 3-7 and 16-33 over PCT Patent Publication WO 97/45367 to Ahola et al. is also traversed. As discussed above, claims 1 and 3-7 have been cancelled.

Claims 16, 18 and 19 recite a method for adjusting a biodegradation rate of a silica fiber spun from a silica sol having

a viscosity of from about 1,000 to less than 100,000 mPas. Ahola et al. also fails to disclose or suggest the viscosity range feature of these claims. Instead, Ahola et al. discloses a method for produced a biodegradable silica fiber using a starting sol viscosity of 10 Mpas (Example 2, page 14, lines 2-3).

Claims 20-23 define a method for adjusting a biodegradation rate of a silica fiber which comprises controlling the viscosity of the silica sol at the starting point of the spinning process, such that fibres spun from an early stage of the spinning process degrade more slowly than fibres spun in a later stage. Ahola et al. fails to disclose or suggest that fibres spun from an early stage of the spinning process degrade more slowly than fibres spun in a later stage.

Claims 30-33 are directed to a controllably biodegradable silica fiber spun from silica sol, a biodegradation rate of the fiber being adjusted by either controlling the starting point of the spinning process by a viscosity of the silica sol wherefrom the fiber is spun, or by controlling the viscosity of the spinning sol, the solubility of the fiber in simulated body fluid being 0.2 to 20 weight percent/hour. Claims 24-27 are directed to a delivery device and pharmaceutical preparation containing the controllably

biodegradable silica fiber of claim 30. Claims 28 and 29 recite a method for administering a biologically active agent to a human or animal which employs a delivery device comprising a controllably biodegradable device of claim 30.

Ahola et al. also fails to expressly disclose (or suggest) biodegradable silica fibres having a solubility in simulated body fluid of 0.2 to 20 wt-%/h. Ahola et al. also fails to inherently disclose the claimed fibres because the reference fails to disclose the viscosity range employed to prepare these fibres.

Reconsideration and withdrawal of the anticipation rejection of claims 1, 3-7 and 16-33 over Ahola et al. are earnestly requested.

The 35 U.S.C. § 103(a) rejection of claims 1, 3-7 and 16-33 over German patent DE 196 09 551 ("German '551") is respectfully traversed. The applicants have unexpectedly discovered a method for adjusting the biodegradation rate of a silica fibre spun from a silica sol, in which the biodegradation rate is adjusted by controlling the viscosity of the spinning sol wherefrom the fibre is spun, such that fibres derived from sols having low viscosity during the spinning process degrade more slowly than fibres derived from sols prepared at a higher spinning viscosity. The resulting

silica fibers are biodegradable such that their solubility in simulated body fluid is from 0.2 to 20 weight percent.

German '551 fails to raise a *prima facie* case of obviousness against the claimed methods and fibers produced therefrom. More particularly, German '551 fails to disclose or suggest that controlling the viscosity of a spinning solution from which the fiber is spun can permit adjustment of the fiber's biodegradability in simulated body fluid. In this regard, spinning sol viscosity is not dependent on the degree of polycondensation of silica fiber. Instead, polymerization of SiO_2 gels proceeds on two levels, by polycondensation and by aggregation of colloidal particles formed by polycondensation. The aggregation behavior of colloidal particles is the main factor controlling the size and form of the aggregates presence in the sol and, thus, also its viscosity.

The claimed fiber has a solubility in simulated body fluid being 0.2 to 20 weight percent/hour. The lower (slower) dissolution limit will result in complete fiber dissolution in

about 21 days.[1] In contrast, German '551 discloses a fiber whose fastest dissolution time is 50 days.

During the interview, Examiner Fubara questioned why the difference in dissolution times would be considered unexpected or surprising to one of ordinary skill in the art. The answer is that silica fibers with fast dissolution rates had not been achieved by the methods of the prior art, and thus those of ordinary skill in the art would not have believed that silica fibres with such a fast dissolution rate (0.2 to 20 weight percent/hour) could be prepared.

One of ordinary skill in the art is given no disclosure or suggestion to modify the fiber of German '551 so as to achieve a solubility in simulated body fluid of from 0.2 to 20 weight percent/hour by controlling the spinning solution's viscosity, either at the start of the spinning process or during spinning, such that fibres derived from sols having low viscosity during the spinning process degrade more slowly than fibres derived from sols prepared at a higher spinning viscosity.

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[1](100 weight %)÷(0.20 weight %/hour)(24 hours/day) = 20.8 days.

German '551 appears[2] to teach that fiber biodegradability can be adjusted by controlling the degree of polycondensation. Thus, it could be argued that controlling the degree of polycondensation permits control of the amount of OH-groups, and thus the biodegradability of the silica fiber.

However, the applicants believe effects discussed above and disclosed by German '551 do not contribute to the biodegradation rate to such an extent that they would be of practical use. More particularly, the applicants believe the polycondensation degree of the sol reaches a rather constant level well prior to when the sol reaches the viscosity window in which fibers can be drawn. In fact, the fiber biodegradation rate would decrease rather than increase with increasing sol viscosity if the polycondensation degree of silica particles in the sol was important to the biodegradation rate. In short, the controllably biodegradable fibers and methods of the present invention do not involve the mechanism taught by German '551, and one of ordinary skill in the art would not be led to the claimed fibers and method by this reference.

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[2]A complete translation of German '551 will be filed upon receipt by the undersigned.

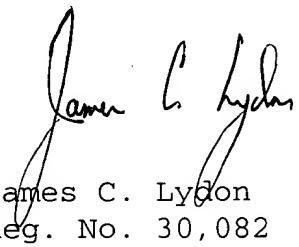
Reconsideration and withdrawal of the obviousness rejection of claims 1, 3-7 and 16-33 over German '551 are earnestly requested.

New claim 34 also defines patentable subject matter over the prior art of record. The applicants have unexpectedly discovered that the biodegradability of a silica fiber can be controlled, i.e., determined, by controlling the starting point of fiber spinning based upon the viscosity of the silica sol (Page 2, lines 25-28). Figures 8, 10 and 12 correlate the biodegradability rate of silica fibers as a function of starting point viscosity of the fiber spinning process for various silica fibers. See also Figs. 13 and 14. One of ordinary skill in the art, seeking to prepare a silica fiber having a particular biodegradation rate, would necessarily correlate a desired biodegradability of the silica fiber with a starting viscosity of the silica sol" using a graph such as those illustrated in Figs. 8, 10 and 12, before preparing the silica sol, and spinning the fiber from the sol, with the spinning step beginning at a sol viscosity value correlating to the desired biodegradability of the resulting fiber. The claimed method is not disclosed or suggested by the prior art of record.

It is not believed any fee is required for entry and consideration of this Amendment. Nevertheless, the Commissioner is

authorized to charge our Deposit Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,



James C. Lydon
Reg. No. 30,082

Attorney Case No.: TUR-115
100 Daingerfield Road
Suite 100
Alexandria, Virginia 22314
Telephone: (703) 838-0445
Facsimile: (703) 838-0447